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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,944	10/31/2000	Hiroshi Fukuda	20498	1795

151 7590 10/30/2003

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EXAMINER	
MORRIS, PATRICIA L	

ART UNIT	PAPER NUMBER
1625	26

DATE MAILED: 10/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/702,944	Fukuda et al
Examiner	**Group Art Unit**
T. Morris	1625

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 8-26-03.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☒ Claim(s) 1-9, 15-18, 22, 23, 26, 27, 30 and 31 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s) 1-9, 15-18, 22, 23, 26, 27, 30 and 31 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Revi w, PTO-948

☐ Other_____

Office Action Summary

DETAILED ACTION

Claims 1-9, 15-18, 22, 23, 26, 27, 30 and 31 are under consideration in this application.

Election/Restriction

Again, this application has been examined with regard to the elected compound wherein Q represents (2R,3R)-3-[4-(4-cyanophenyl)thiazol-2-yl)]-2-(2,5-difluorophenyl)-1-(iH-1,2,4-triazol-1-yl)-butan-2-0l, R^3 is (optionally substituted) pyridin-2-yl and R^1, R^2 and X as set forth in claim 1, exclusively. It is suggested that the nonelected compounds be deleted.

The restriction requirement is deemed sound and proper and is hereby made final.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> > (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
> >
> > (f) he did not himself invent the subject matter sought to be patented.

Claims 1-9, 15-18, 22, 23, 26, 27, 30 and 31 are rejected under 35 U.S.C. 102 (e) and/or (f) as being anticipated by Hayase et al. for the reasons set forth in Paper nos. 7, 14 and 23.

Again, the references specifically recite the instant compound.

The precursor and final product are not different products, regardless of differences in their activity and efficacy. See *Marion Merrell Dow Inc v. American Cyanamid Co.*, 36 USPQ2d 1036. Hence, the instant compound is deemed to be anticipated therefrom.

Applicants assert that the fact that applicants' compounds may be enzymatically cleaved in the body to generate the parent compound does not make the compounds the same as the parent compounds. They are in fact the **same** compounds. Applicants have **failed** to provide any **objective evidence that the compounds are in fact not the same.** Attorney's arguments do **not** take the place of objective evidence.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 15-18, 22, 23, 26, 27, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayase et al. in view of Hudyma et al. and Davidsen et al. for the reasons set forth in Paper nos. 7, 14 and 23.

As set forth in Paper no. 7, Hayase et al. disclose the final product having the same use. Note compound in lines 5-6 in column 5 therein. Further Hudyama et al. teach that analogous amine salts of triazoles similar to those of the claimed invention retained the activity associated

with the final products, whereas Davidsen et al. teach that pyridine salts are known to be extremely soluble. In view of the structural similarity between the compounds of the instant claims and those of Hayase et al. and that the substituent connected with the differentiating feature is lost *in vivo*, one of ordinary skill in the art would expect that the claimed compounds would have antifungal activity. It is well settled that the final product and its precursor are not different products, regardless of differences in their activity and efficacy. *Marion Merrell Dow Inc. V. American Cyanamid Co.*, supra.

Again, applicants appear to argue that one having ordinary skill in the art would not have been motivated to produce the compounds encompassed by the claims. The motivation is not abstract but is always related to the properties or uses that one having ordinary skill in the art would have expected the resulting compound to exhibit. In situations involving chemical compounds bearing a close structural similarity, the requisite motivation stems from the expectation that compounds exhibiting closely similar structures will exhibit similar properties. In the situation here, the final product and its precursor are not different products. As previously discussed, the requisite motivation for producing the claimed compounds stems from the fact that it is expected that the final products will have antifungal activity. No unexpected or unbvious properties are noted.

Again, the Declaration of Unemda, while interesting, is of little if any probative value because it fails to include the final product and the elected compound. Moreover, the claims are directed to using the instant compounds for the treatment of fungicidal infections. Also note page

35 of the specification. Again, the declaration is silent as to whether the compounds treat any fungal infection. Further, the declaration is not commensurate in scope with the claims. It is expected that the final product and its precursor will possess fungicidal activity. No unexpected or unobvious results are noted. Again, applicants have **failed to provide any objective evidence** that the instant compound actually treats **any fungal infections**. Applicants are invited to note the instant method claim is directed to the **treatment of fungal infections.**

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No support can be found for all hydrolizable acyl groups. This appears to be an attempt by applicants to claim any and all unknown compounds metabolized by the body.

Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The expression acyl group is a hyrolizable group is now employed in claims 3 and 4 with no indication given as to what the acyl groups really are. Further, applicants are now claiming any unknown metabolites formed *in vivo*.

One should be able, from a reading of the claims, determine what that claim does or does not encompass.

The written description is considered inadequate here in the specification. Conception of the intended acyl groups and the corresponding metabolites should not be the role of the reader. Applicants should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 USC 112, first paragraph. If you (the public) find that it works, I claim it, is not a proper basis of patentability. In re Kirk, 153 USPQ 48, at page 53.

Contra to applicants' arguments in the instant response, one cannot tell from a simple reading of the claim what is being claimed. One must first conceive of the acyl group and now its metabolite. Then one must, by preparing the compound himself, determine if the acyl group works or not. Where is the specific claiming and distinctly pointing out? How can applicants regard as their invention inexact concepts? The breadth of which they could not have possibly checked out with representative exemplification. The terms are not finite.

Applicants are claiming a compound of the formula. Pure chemistry, a compound. Not a resin of general property ranges, but a pure compound. That compound used for any purpose is taken from the public in a 20-year monopoly to applicants. Then, the public is entitled to know what compound they cannot use. Yet, the claim is not specific to that compound. The public cannot tell what they may not use. How is a claim of the instant breadth defensible in an infringement action?

As applied to pure compounds, In re Cavallito and Gray, 134 USPQ 370, and In re Sus and Schaefer, 134 USPQ 301, are considered to set the proper applicable standard of required definiteness and support.

Conclusion

Applicant's arguments filed July 30, 2002 have been fully considered but they are not persuasive.

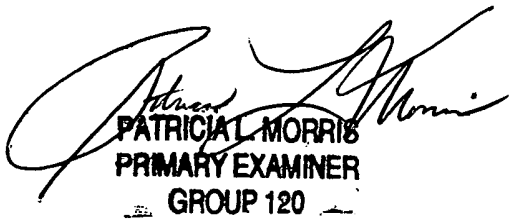
No claim is allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Morris whose telephone number is (703) 308-4533. The examiner can normally be reached Mondays through Fridays.



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October 29, 2003